Expanding Treatment for Atrial Fibrillation : New Drug and New Indications for Catheter Ablation

### Francis Marchlinski M.D.



### **Presenter Disclosure Information**

Within the past 12 months, the presenter has received financial support from the organizations identified below for the relationships listed.

Company Name:	<u>Relationship:</u>
Biosense Webster	Sponsored Research/Advisory Panel
Boston Scientific/ Guidant	Lecture Honorarium
St. Jude Medical	Sponsored Research/ Lecture Honorarium
Medtronic	Sponsored Research/ Lecture Honorarium
Sanofi Aventis	Advisory Panel

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Dronaderone

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### New Drug:

Dronaderone

New Indications for Catheter Ablation: Persistent AF /Permanent AF (> 1 year)? Patients with low LVEF? Elderly? Primary Therapy – Before Drugs?



Amiodarone (MW=682)

#### 1980 - first introduced from Europe

- Antihypertensive
- Antianginal
- Antiarrhythmic
- Once a day therapy



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### Add to the drinking water?

#### **Dronedarone vs Amiodarone**



Amiodarone (MW=682)



SR33589B/Dronedarone (MW=593)





<b>Dronedarone Trial</b>	Findings
European Trial in AF or A Flutter Patients Receiving Dronedarone for the Maintenance of Sinus Rhythm (EURIDIS)	AF Control 33% with dronedarone, 22.5% with placebo
American–Australian–African Trial with Dronedarone in AF or A FLPatients for the Maintenance of Sinus Rhythm (ADONIS)	AF Control , 39%, with dronedarone, 25% with placebo

Efficacy and Safety of Dronedarone versus Amiodarone for the Maintenance of NSR in Patients with AF (DIONYSOS) Rate of AF Control **37%** with dronedarone, **58%** with amiodarone, but significantly fewer adverse effects with dronedarone



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### **Dronedarone Trial**

#### **Findings**

Antiarrhythmic Trial with Dronedarone in Moderate to Severe CHF (LVEF <35%) Evaluating Morbidity Decrease (ANDROMEDA) - AF Not Required Doubling of death rate in the dronedarone group, predominantly due to cardiovascular causes

#### **Dronedarone Trial**

#### **Findings**

A Placebo-Controlled, Double-Blind, Parallel Arm Trial (4628 pts) to Assess Efficacy of Dronedarone 400 mg bid for Prevention of CV Hospitalization or Death from Any Cause in Pts with AF /A FL (ATHENA) and risk factors for stroke Significant reduction in the rate of composite end point of death from cardiovascular causes and hospitalization due to CV events 36% versus 29% ;(Mostly AF (19.6% vs 12.7%). Increased incidence of GI intolerance ( 4 %); no other toxic effects

### **Dronedarone Trial**

### **Findings**

Athena Study	Dronedarone	Placebo
CV Hospitalization or Death	36%	29%
AF Related Hospitalization	19.6%	12.7%

# Dronedarone

### Dronedarone

#### **FDA Approved Indication:**

to reduce the <u>risk of cardiovascular hospitalization in</u> <u>patients with paroxysmal or persistent AF</u> or atrial flutter (AFL) with a <u>recent episode of AF/AFL</u> and associated cardiovascular risk factors

- -age > 70,
- -hypertension,
- -diabetes,

-prior cerebrovascular accident,

-left atrial diameter  $\geq$  50 mm

-left ventricular ejection fraction (LVEF < 40%), who are in sinus rhythm or who will be cardioverted

#### "Black Box Warning"

SHOULD NOT BE ADMINISTERED TO 1) Any patient with EF <= 35% with a recent < 30 days) hospitalization for heart failure.

#### **SHOULD BE DISCONTINUED IN**

1) Any patient with EF <= 35% who is hospitalized for heart failure.

2) Reinitiation should not occur until stable at least 30 days following discharge.

"Black Box Warning"

### **ANDROMEDA** and **ATHENA**:

Types of Patients	ATHENA	ANDROMEDA	
No symptoms of CHF	Vee	No	
EF > 0.35	Tes		
EF ≤ 0.35	Stable with	Recently unstable	
Class II CHF	nonpermanent	without indication	
Class III CHF	atrial fibrillation	for dronedarone	
Class IV CHF	No	Yes	
History of atrial fibrillation	Yes	No	

Differences between ANDROMEDA and ATHENA may have been due to lack of overlap in types of patients enrolled in the ANDROMEDA and ATHENA trials.

# Selection of Patients With AF for Treatment With Dronedarone

Types of Patients	ATHENA-Type Patients	ANDROMEDA-Type Patients	
No symptoms of CHF	If clinically stable during the past		
EF > 0.35	month		
EF ≤ 0.35	If clinically stable during the past month	If hospitalized for heart failure or class IV symptoms within the last month	
Class II CHF			
Class III CHF			
Class IV CHF		If hospitalized for	
No past or current AF		IV symptoms within	
		the last month	
	APPROPRIATE USE	INAPPROPRIATE USE	

### ANDROMEDA and ATHENA: Summary of Findings

2. The effects of dronedarone in ATHENA differed dramatically from those in ANDROMEDA.

	ANDROMEDA		ATHENA	
Drug	Placebo	Dronedarone	Placebo	Dronedarone
All-cause mortality	12	25	139	116
Cardiovascular Hospitalizations				
Supraventricular arrhythmia	1	4	457	296
Heart failure	30	35	92	78
Myocardial ischemia	8	13	61	48
Cerebrovascular accident	3	4	35	28

Other Contraindications: -Second or Third Degree AV Block -Sinus node dysfunction Bradycardia <50 bpm

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- -Exaggerated bradycardia with Beta Blockers/Calcium channel blockers

### Dronedarone

#### DOSING:

There is only one dose 400 mg PO Q12 hrs
Increase in dronedarone concentration: Women (130%); Asian men (100%); Elderly (123%)

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3) Does not need a loading protocol.

#### CYP 3A4 Metabolism

Marked CYP 3A4 Inhibitors contraindicated: ketocanozole, clarithromycin, nefadozone etc.

-Moderate Inhibitor-

-Grapefruit Juice 2.5 X Increase in dronedarone -Statins - 2-4X increase - (rhabdmyolysis)

-Modest Inhibitors -verapamil, diltiazem 1.4-1.7 X  $\uparrow\uparrow~$  – and vice versa

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New Indications for Catheter Ablation: Persistent AF (CV or >1 week)?/Permanent AF (>

1 year)? Patients with low LVEF? Elderly? Primary Therapy – Before Drugs?

#### 80+ % of triggers initiating AF from PVs

RIPV



Haissaguerre M: NEJM 1998



# Pulmonary Vein (PV) Origin for Triggers Initiating Atrial Fibrillation Evolution of Therapy



## Standard Catheters and Catheter Placement

- Multipolar catheters in right and left atrium, coronary sinus
- Double transseptal guided by Intracrdiac Echo – Circular mapping catheter (broken arrow) and mapping/ablation catheter in LA.
- Muscle sleeves of pulmonary veins isolated

#### Shallow LAO XRAY



#### **AF Ablation Strategies**



# A fib Management Guidelines ACC/AHA/ESC



#### Circumferential PV Catheter Ablation vs Antiarrhythmic Drugs (Randomized Trials)

#### **Total Randomized – 432 patients**



Noheria et al. Arch Intern Med. 2008;168(6):581-586 (A).

►<u>52 year old man</u> with hypertension  $\geq$  Paroxysmal AF; symptomatic with palpitations ►LA size 4.4 cm and normal LV ➤Tried and failed sotalol



Case 1 ►<u>52 year old man</u> with hypertension  $\geq$  Paroxysmal AF; symptomatic with palpitations LA size 4.4 cm and normal LV Tried and failed sotalol

# "Consider for Catheter Ablation"

## Drugs versus Ablation for Paroxysmal Atrial Fibrillation

Prospective randomized (2:1 ablation versus drug) multicenter trial (19 centers)

Entry criteria  $- \ge 3$  AF episodes and failed antiarrhythmics (82%) or AV nodal blocker (18%)

Study stopped after first interim analysis (167 patients enrolled)

Wilber et al Circulation 2008 (AHA Abstract Presentation ) preliminary data

#### **PAF - Drug Versus Ablative Therapy**



Wilber et al Circulation 2008 (AHA Abstract) preliminary data

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# Case 2

- 64 year old man with <u>persistent AF</u> symptomatic with exertional dyspnea (<u>no palpitations</u>)
- Trial of sotalol and cardioversion failed
- Side effect s beta blockers and calcium blockers
- Heart rate 94 bpm at rest on office ECG despite metoprolol XL – 50mg bid; diltiazem 240mg qd; digoxin .25mg qd
- LVEF 38% by echocardiogram

# **Atrial Fibrillation Ablation Procedures**

N= 2321 procedures





#### PV Isolation Plus Elimination of Non-PV Triggers (follow-up >12 mo)



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Persistent/Long Lasting Persistent Afib (Bordeaux Technique – Step Wise Approach) 1) PV Isolation

2) SVC and CS isolation – elimination or dissociation of potentials

**3) Atrial Ablation** 

**Complex and fractionated Egs** 

Regions with short cycle length compared to the LAA

**Regions with a gradient of activation** 

4) Linear ablation

RA CT Isthmus/LA Roof /Mitral Isthmus – Complete conduction block

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RA CT Isthmus/LA Roof /Mitral Isthmus – Complete conduction block 23 AF 108 AT 22 NSR 120 NSR

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RA CT Isthmus/LA Roof /Mitral Isthmus – Complete conduction block

120 NSŘ **REDO - 80 (52%)** 15 (10%) **65** (43%) for AF for AT 121 (79%) NSR off meds/ 133(87%)

on meds



#### Success for Persistent/Long Standing Persistent AF after Repeat Procedures

Study (No of Pts)	Procedure	% of Repeat	No AF/AT %*	F/U(mos)
Elayi et al (48)	PVAI	40%	60% <b>(84%)</b> *	14.6
Elayi et al (49)	PVAI+CFAE	53%	81%( <b>94%)</b> *	14.6
Oral et al (50)	PVAI	58%	68%	9
Oral et al (50)	PVAI + CFAE	52%	60%	9
Penn( 262)	PVAI +Triggers	45%	57% <mark>(81%)</mark> *	28
O'Neill et al(153)	Stepwise Approach	100% **	79% ( 87%)*	30

\* Number in parenthesis is control on Antiarrhythmic drugs

\*\* 65 out of 80 pts (81%) for Atrial Tachycardias after AF ablation
## AF Ablation Effect on LV Ejection Fraction: 48 Patients With Low LVEF



### Pre-Ablation Diagnosis – Nonischemic Cardiomyopathy

Gentlesk et al. J Cardiovasc Electrophysiol. 2007;18(1):9-14 (B).

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Ablation – Time 0

LVEF2 Post-Ablation

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## Impact of AF Ablation on LVEF – Bordeaux Experience



Hsu L-F: NEJM 2005

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## **Consider AF Ablation!!**

- 64 year old man with persistent AF symptomatic with moderate exertional dyspnea (no palpitations)
- Some fatique, constipation, erectile dysfunction on beta blockers and calcium blockers
- Heart rate 94 bpm at rest on office ECG despite metoprolol XL – 50mg bid; diltiazem 240mg qd; digoxin .25mg qd
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## **Consider AF Ablation!!**

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New Indications for Catheter Ablation: Persistent AF (CV or >1 week)?/Permanent AF (> 1 year)? Patients with low LVEF? Elderly?



- <u>80 year old man</u> with paroxysmal atrial fibrillation symptomatic with palpitations and dizziness
- Rates 150-160 bpm in AF
- Did not tolerate amiodarone
- Sotalol and propafenone tried and ineffective
- Referred for His Bundle ablation and pacemaker

## Effect of Age on Long-Term (>12 mo) AF Ablation Outcome



## Major Complications (Overall 2.0%)



From Zado et al. J Cardiovasc Electrophysiol. 2008.

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From Zado et al. J Cardiovasc Electrophysiol. 2008.



### **Elderly Patients (>75years)**

#### 174 pts underwent PVI

Procedural Acute Complications





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# Consider AF Ablation and Avoid His Ablation !!

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➤ 45 year old with monthly episodes of atrial fibrillation symptomatic with dizziness.

## >No prior drug trial

≻Transtelephonic monitoring →



**Referred for pacemaker and drug therapy** 

## Non PV Triggers (N=137) Initiating Atrial Fibrillation in 113/761 patients(15%)





# Outcome ( > 3 month follow-up)

	No or rare AF off Meds	No Afib + Off Meds	Average Follow-up mos
Only Non PV Trigger (n - 23 pts)	23 (100%)	22 (96%)* *P<.05	30 ± 17



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Persistent AF (CV or >1 week)/Permanent AF (> 1 year) -Yes

Patients with Low LVEF - Yes

Very Elderly - Yes (May be increased risk)

Primary Therapy – Before Drugs - ? Yes in Selected Pts